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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,314	11/26/2003	Hanshermann Franke	30572/39753A	6830
4743 7590 10/09/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/723,314

Applicant(s)

FRANKE ET AL.

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,21 and 23-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21 and 23-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/26/2003 as amended 4/2/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: ____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:20050713,20041029,20040712,20050713.

Art Unit: 1616

DETAILED ACTION

Claim Objections

Claims 1, 6-16, 23,28,30, 33-37 are objected to because of the following informalities:

Claim 1, “d(0.1) –“, “d(0.5) =” and “d(0.9) –“ is not consistent with “d(0.1):“ “d(0.5):” and “d(0.9):“ setforth in claim 21.

Claim 6 has the claim status modifier “(previously presented)”, however, in the second line of the claim the colon mark is underlined, i.e. the claim is currently amended.

Claims 6-16, 23,28,30, 33-37 use period marks in the body of the claim. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Further, if the Applicant intends to retain the identification of subparagraphs by using letters, the Applicant should not interchange uppercase and lowercase letter for the same component.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 21, 23-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention:

Art Unit: 1616

The claim invention is directed to pharmaceutical compositions, methods of preparation and methods of treatment in which the composition contains oxcarbazepine having a specified particle size distribution and release rate resulting, in some of the dependent claims, in the specified plasma concentration of the oxcarbazepine and metabolite monohydroxydihydrocambazepine. Claim 23 claims a capsule or pouche containing said oxcarbazepine which was mixed with other excipients and compacted and screened such that the screen material has the claimed particle size distribution.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses tablets containing Trileptal ® (600 mg oxcarbazepine), HPMC, silica, magnesium stearate, croscopolvidone in the core and a coating of HPMC, dye, PEG, talcum and titanium dioxide (WO 01/32183 (Norvartis) Pages 13, 14). Although, the Applicant's specification does not indicate the formulation of the comparative tablet, the Specification indicates that the tablet containing 600 mg oxcarbazepine was customary in the trade (Trileptal of the company Norvartis). As such, the Examiner assumes that the above tablet was what was tested. As such, although the prior art tablet contained the same amount of oxcarbazepine, the excipients, formulation process, etc. resulted in a different release rate and plasma concentration. Further, this is supported by other prior art which indicates that coatings and matrix characteristics, particle size, diluents, disintegrants, binders, granulating agents, lubricants, methods of granulation and compression (compression force has a significant influence on disintegration and particle size) on dissolution rates (Remington's (18th Ed. 1990), page 1684, Remington's (17th Ed. 1985), pages 655-658). As such, predictability in the art is low as to what

Art Unit: 1616

combination of ingredients and dosage formulations will result in the claimed release profile and plasma concentration.

The amount of direction or guidance present and the presence or absence of working examples:

The only example tested was a tablet containing 600 mg oxcarbazepine, ammonium methacrylate copolymer, sodium carboxymethyl starch, magnesium stearate and microcrystalline cellulose, however, the compression force is not disclosed, the tablet has no coating and there is no indication that the oxcarbazepine or compacted material containing said oxcarbazepine had the claimed particle size distributions (Specification, paragraphs 0055-0062). WO 03/101430 which is related to the present application discloses the exact same tested tablet, testing procedures and the same release profile and plasma concentration, however, unlike the present Application there is no disclosure relative to particle size distribution (WO 04/101430, pages 9-11). The English language version is US 2004/0185095. As such, there is no evidence that the claimed particle size distribution will result in the claimed release profile and plasma concentration.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that the claims 1-5, 18,19, 21, 41, 42 are generally only limited by the particle size distribution of and release rate of oxcarbazepine, claims 6-17, 23-40, 43,44 indicate various additional ingredients, however, the compression force is not disclosed with respect to the tablets and some of the claims are directed to capsules or pouches. Given that particle size, compression force, the presence of excipients, etc. affect dissolution and plasma concentration and the only example tested was a tablet formulation having no coating, specific

Art Unit: 1616

amounts of active agent and excipients in which the compression force was not disclosed, one of ordinary skill in the art would be required to due undue experimentation in order to determine what combination of compression force, particle sizes, core excipients, coatings and coating excipients, dosage forms (powders, granules, encapsulated powders and granules, sustained release forms, capsules, pouches, etc.) and formulation processing steps, will result in the claimed release profile and plasma concentration.

Conclusion

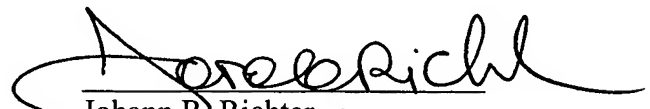
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
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September 29, 2007



Johann R. Richter
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